Department of LABOR AND INDUSTRIES

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PROVIDER BULLETIN

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THIS ISSUE

"Spinal Cord Stimulators (SCS) for Injured Workers with Chronic Low Back and Leg Pain after Lumbar Surgery" Pilot Study

TO:

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Dolorologists
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CONTACT:

Provider Hotline
1-800-848-0811
From Olympia 902-6500

LaVonda McCandless, RN
Occupational Nurse Consultant
mlav235@Lni.wa.gov

Purpose

This Provider Bulletin **REPLACES PB 04-17** and amends the inclusion criteria for the pilot study entitled "Spinal Cord Stimulators (SCS) for Injured Workers with Chronic Low Back and Leg Pain after Lumbar Surgery" that pertains to State Fund claims in all locations. This Bulletin is currently in effect. The SCS pilot study inclusion criteria have been amended to increase participation in the study. The amended inclusion criteria are:

- Patient has an open, compensable Washington State Workers' Compensation claim for a back injury and is receiving time loss compensation;
- Patient has undergone 1,2, or 3 open lumbar surgeries within the duration of their current Washington State Workers' Compensation claim; and
- Patient's age is equal to or between 18 and 60 years.

All other inclusion criteria remain the same and are printed at the back of this Provider Bulletin.

Spinal Cord Stimulation

Spinal cord stimulation (SCS) involves the insertion into the epidural space of electrodes that are connected to an internal or external electrical pulse generator[1]. Based on the gate control theory of pain proposed by Melzack and Wall,[2] electrical impulses generated by the SCS are thought to inhibit the conduction of pain signals to the brain. SCS has been used to treat chronic low back and leg pain that has failed to respond to spine surgery and complex regional pain syndrome (CRPS) Type I.

A randomized controlled trial of SCS in patients with CRPS concluded that SCS combined with physiotherapy reduced pain significantly more than physiotherapy alone, but did not improve functional status at 6 months and 2 years post-implantation[3][4]. Based on European cost figures, these researchers also speculated that, if pain reduction is maintained in the long term, then SCS might be a cost-effective intervention[5].

[1] North RB and Wetzel FT. Spinal cord stimulation for chronic pain of spinal origin: a valuable long-term solution. *Spine* 2002;27(22):2584-2591; discussion 2592.
[2] Melzack R and Wall PD. Pain mechanisms: A new theory. *Science* 1965;150:971-979.
[3] Kemler MA, Barendse GA, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *N Engl J Med* 2000;343(9):618-624.
[4] Kemler MA, De Vet HC, et al. The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. *Ann Neurol* 2004;55(1):13-18.
[5] Kemler MA and Furnee CA. Economic evaluation of spinal cord stimulation for chronic reflex sympathetic dystrophy. *Neurology* 2002;59(8):1203-1209.

The evidence supporting the efficacy of SCS for chronic low back and leg pain is primarily from case series studies. Due to the paucity of the evidence, several reviewers have concluded that, although SCS may be associated with pain relief in many patients, the efficacy of SCS remains unproven.[6][7][8]

Coverage of SCS

SCS is a noncovered procedure for State Fund claimants. However, the **department will cover SCS for State Fund claimants if performed as part of the SCS pilot study conducted by the University of Washington**. The study is entitled, "Spinal Cord Stimulators (SCS) for Injured Workers with Chronic Low Back and Leg Pain after Lumbar Surgery."

Payment authorization will be contingent upon the patient consenting to participate in the study, meeting the study inclusion criteria, and completing the baseline assessment.

The SCS Pilot Study

Researchers at the University of Washington (UW) are conducting a non-randomized, prospective study of spinal cord stimulation for injured workers with chronic low back and leg pain following previous lumbar spine surgery.

The SCS pilot study addresses several research questions:

1. What is the proportion of injured workers receiving workers' compensation benefits with chronic low back and leg pain (LBP) following previous spine surgery who show improvement one year and two years after SCS implantation?
2. How do the outcomes of SCS recipients compare to outcomes of other injured workers with chronic LBP and prior spine surgery who receive: a) usual care; or b) multi-disciplinary pain clinic treatment?
3. What is the estimated per-patient direct cost of medical care and time loss compensation (wage replacement payments for lost work time) to the Department of Labor and Industries over a period of 18 months in the SCS and comparison groups?
4. What are the types of complications and adverse events associated with SCS, and their prevalence, in the first 18 months after SCS implantation in a group of injured workers with chronic LBP and prior spine surgery?

The primary study outcome at 12-month follow-up will be the proportion of patients who achieve 50% or greater reduction (relative to baseline) in leg pain AND less than daily narcotic medication use AND a 2 point or greater improvement on the Roland function scale. Outcomes will also be calculated at 24-months.

[6] Turner JA, Loeser JD, et al. Spinal cord stimulation for chronic low back pain: a systematic literature synthesis. *Neurosurgery* 1995;37(6):1088-1095; discussion 1095-6.
[7] Stocks RA and Williams CT. Spinal cord stimulation for chronic pain. Southampton: University of Southampton, 2001.
[8] Turner JA, Loeser JD, et al. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications. *Pain* 2004;108;137-147.

Secondary outcomes will be baseline to follow-up change in leg pain, back pain, physical disability, and depressive symptom severity; cumulative number of time loss days; compensation status at follow-up; complications; medical costs in the 18 months after the baseline interview; time loss compensation costs in the 18 months after the baseline interview; self-reported work status at follow-up; self-reported symptom satisfaction at follow-up; and self-reported change in pain and function at one year and two years.

The study aims to observe SCS outcomes in routine practice. Therefore, individual physicians will conduct the implantation procedure and provide follow-up care. Individual physicians will also choose the length of the trial SCS period, the type of SCS device, and the type of pulse generator.

Pilot Study Population

The SCS intervention group will be compared to two comparison groups. The comparison groups will comprise injured workers with chronic LBP who meet inclusion and exclusion criteria for SCS, but who have not been offered SCS by their physician. The first comparison group will receive usual care for their symptoms. The second comparison group will receive treatments at multi-disciplinary pain clinics.

The study aims to provide information on 30 patients with permanent SCS implants over a two-year period. Therefore, 50 injured workers will be recruited to undergo a trial of SCS in order to take into account likely loss to follow up and patients with an unsuccessful trial. The study also aims to recruit 50 patients each to two comparison groups.

Criteria Determining Study Eligibility

Inclusion Criteria[9]	Exclusion Criteria[10]
• Low back pain has radiated into one or both legs for more than 6 months. • Radicular pain is greater than axial pain. • Average leg pain in the last month is rated as greater than 5 on a 10-point rating scale. • Patient has undergone one, two, or three open lumbar spine surgeries within the current claim. • Patient is able and willing to use the SCS. • Patient understands the limits and risks of the therapy. • Patient has an open, compensable Washington State workers' compensation state fund claim for a back injury and is receiving time loss compensation.	• Patient has had more than 3 prior open lumbar spine surgeries. • Patient shows progressive motor deficit. • Patient shows progressive bony deformity. • Surgery is contraindicated for the patient. • Patient has had a prior SCS trial or implantation. • Patient has a current cancer diagnosis. • Patient has diabetes. • The patient's age is less than 18 years or greater than 60 years. • The patient's claim duration is more than 3 years at baseline. • A self-insured employer covers the claim. • The patient is unable to complete interviews in English or Spanish. • The patient does not have access to a telephone. • The patient does not consent to participate in the study.

[9] Patient must meet **all** inclusion criteria to enter study.
[10] The presence of any of the listed exclusion criteria will prohibit entry into the study.

Recruitment for the Pilot Study

In order to participate in the SCS intervention group, the injured worker's physician must provide the worker with a copy of the study information sheet. The physician will also send a request for SCS to the department's Utilization Review (UR) vendor, Qualis Health. The request must include BOTH of the following forms.

1. Standard UR information form needed for UR to begin
2. Baseline screening form assessing the inclusion and exclusion criteria

Both of these forms and the information sheet are available online at:
http://depts.washington.edu/niamscrc/scs/forms.html.

The UR nurse will forward to the UW research team the screening forms of injured workers who presumptively meet all of the inclusion and exclusion criteria. Then, the UW research team will contact the patient by telephone to confirm eligibility and to obtain patient consent to participate in the study. At this time, the patient will also complete the baseline assessment. Finally, the Office of the Medical Director will authorize reimbursement for SCS implantation for study participants who meet eligibility requirements and who consent to participate in the study. (See Chart 1)

The study also includes two comparison groups. The department will identify from its administrative database injured workers who are potentially eligible for the usual care comparison group. The pain clinic comparison group will be prospectively identified as injured workers are referred for authorization for multi-disciplinary pain clinic treatment.

Injured workers who are potentially eligible for inclusion in the two comparison groups will receive a mailing from the department. In addition to a consent form, the mailing will include an information sheet that describes the study and indicates that the UW research team will contact them within one week. Finally, the information sheet lists a UW telephone number that injured workers may call if they do not wish to participate in the study.

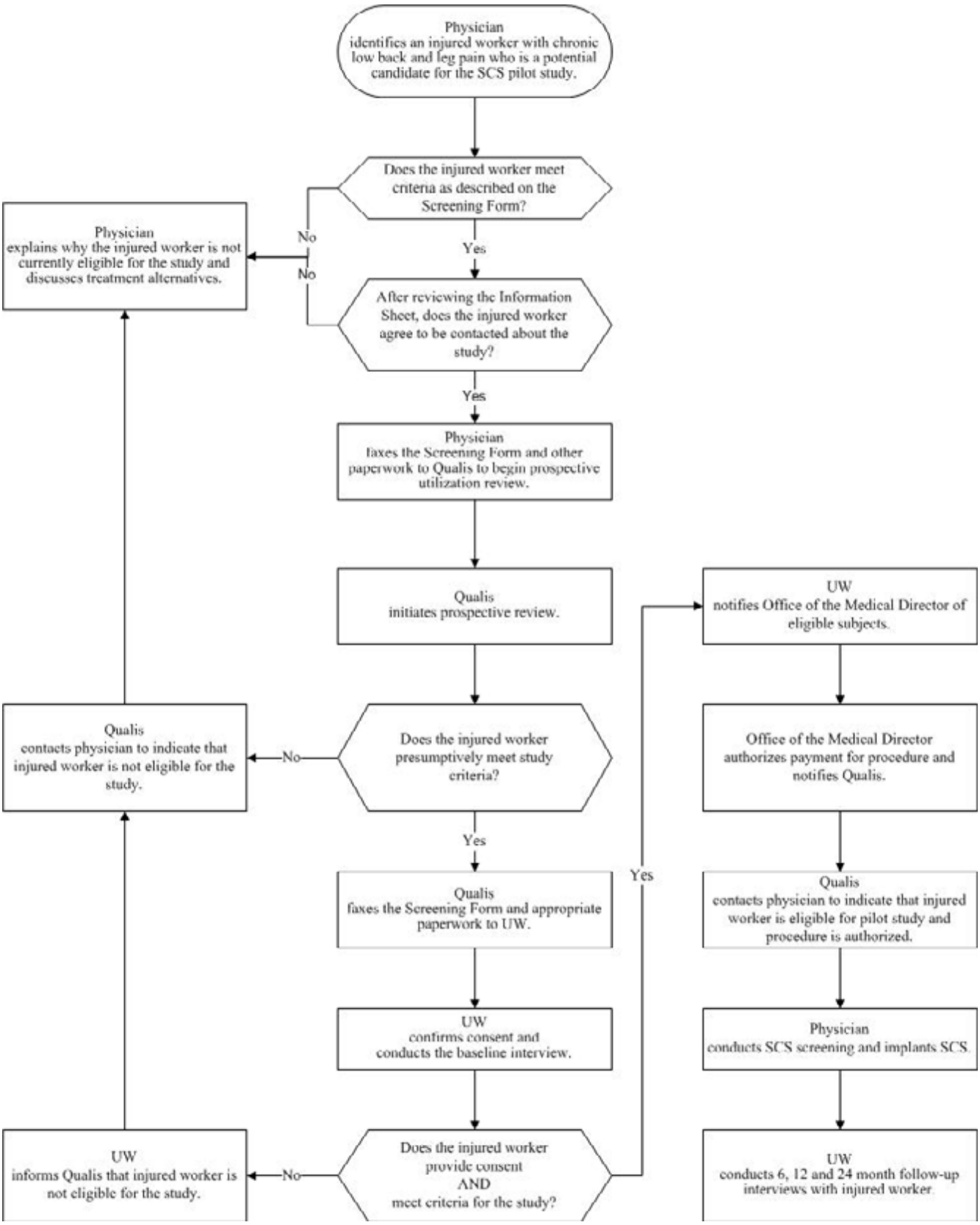
For more information

You may find forms for the study and more information about the University of Washington research team at http://depts.washington.edu/niamscrc/scs/forms.html. You may also request forms by e-mailing niams@u.washington.edu.

Information about the department's utilization review vendor, Qualis Health, may be accessed in Provider Bulletin 02-04. The bulletin is available online at http://www.lni.wa.gov/ClaimsInsurance/Files/Providers/ProvBulletins/PbFiles/PB_02-04.pdf. Qualis Health may be contacted at (800) 541-2894 or (206) 366-3360.

Questions about the department's role in the study may be directed to LaVonda McCandless at mlav235@Lni.wa.gov.

Chart 1. Process flow for recruiting and enrolling patients for the SCS treatment group



QUALIS HEALTH
advancing healthcare • improving health

REQUEST FOR REVIEW FORM

TYPE OF REVIEW:
INPATIENT, OUTPATIENT, RETRO,
RE-REVIEW (EXPEDITED, STANDARD)
(Please circle the appropriate one)

Patient Information

Name: _____ Claim #: _____

Date of Birth: _____ Date of Injury: _____ Social Security #:_____

Requesting Physician Information

Physician: _____ L&I Provider #: _____

Office Contact: _____

Office Phone #: _____ Office Fax # _____

Best time for Qualis Health to contact the physician: _____

Dates of Service: _____Requested Length of Stay: _____

Facility Name: _____ L&I Provider #: _____

Facility Phone #: _____

Procedure Information – SIDE OF BODY: Right OR Left
LEVEL OF SPINE _____

ICD9-CM Diagnosis Code: _____ CPT Code(s): _____

Procedure Description _____

Indications for Surgery_____

_____

_____

_____

_____

Chart notes attached: Y / N (Please circle one) _____ **Number of Pages:**

Please fax this form to
Qualis Health at (877) 665-0383
or mail to: P.O. Box 33400
10700 Meridian Ave. N, Suite 100
Seattle, Washington 98133-9075

Spinal Cord Stimulator Study – SCS SCREENING FORM

Patient Information

Name: First: _____ Middle initial: _____ Last: _____

Claim #: _____ SSN#: _____

Daytime telephone: _____

Evening telephone: _____ Alternate telephone number: _____

Date of Birth: _____ Date of Injury: _____

Mailing address: Street: _____

City: _____ Zip: _____

Requesting Physician Information

Physician: _____ L&I provider #: _____

Office Contact: _____

Office Phone #: _____ Office fax #: _____

Best time for Qualis to contact physician: _____

Procedure information

Proposed date of SCS trial implantation: _____

Facility name: _____ L&I Provider #: _____

Facility Phone #: _____

ICD9-CM Diagnosis Code: _____ CPT code(s): _____

Indications for Surgery (Please also complete screening form on next page)

_____

_____

_____

_____

Chart notes attached: Y / N (Please circle one) Number of Pages:

Please complete the authorization criteria on the next page,
Prior authorization cannot begin until we have confirmed that the patient meets these criteria

Authorization Criteria (to be completed by the physician)

Authorization Criteria	Circle one	
1. Patient has an open, compensable Washington State Workers' Compensation claim for a back injury and is receiving time loss compensation	YES	NO
2. Patient's claim is paid for the state fund and not by a self-insured employer	YES	NO
3. Patient has undergone 1,2, or 3 open lumbar spine surgeries within the duration of their current Washington State Workers' Compensation claim	YES	NO
4. Patient's age is equal to or between 18 and 60 years	YES	NO
5. Patient has low back pain radiating into one or both legs for more than 6 months	YES	NO
6. Patient's radicular pain is greater than axial pain	YES	NO
7. Patient's average leg pain in the last month rated as greater than 5 on a (0-10) rating scale	YES	NO
8. Patient has not had previous spinal cord stimulator implantation or trial	YES	NO
9. Patient does not have progressive motor deficit or bony deformity	YES	NO
10. Patient does not have diabetes or a current diagnosis of cancer	YES	NO
11. Patient does not have any contra-indication for surgery	YES	NO
12. Patient has read the study information sheet, has had a chance to ask questions about the study and spinal cord stimulator procedure, and is willing to be contacted about study participation.	YES	NO

If the patient meets all of the above criteria,
Please fax **all 3 pages** of these forms to
Qualis Health at **(877) 665-0383**
Or mail to:
10700 Meridian Ave N, Suite 100
Seattle, WA 98133-9075

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PO Box 44322
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